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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,387	03/06/2002	Naoki Midoh	2002-0317A	2875

513 7590 07/23/2004

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 07/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/070,387	Applicant(s) MIDOH ET AL.	
	Examiner David J Steadman	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-17 is/are pending in the application.
- 4a) Of the above claim(s) 2-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 13 and 15-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Application

- [1]** Claims 1-13 and 15-17 are pending in the application.
- [2]** Applicants' amendment to the claims, filed June 21, 2004, is acknowledged. This listing of the claims replaces all prior versions and listings of the claims.
- [3]** Applicants' amendment to the specification, filed June 21, 2004, is acknowledged.
- [4]** Receipt of an English language translation of Japanese Patent Application No. 2000-104291 is acknowledged.
- [5]** Applicants' arguments filed on June 21, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.
- [6]** The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.
- [7]** Claims 2-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.
- [8]** Claims 1, 13, and 15-17 are being examined on the merits.
- [9]** In order to clarify the record, it is noted that the examiner incorrectly listed the pending claims at page 2 of the last Office action. A correct listing of pending claims is stated at page 14 of that Office action.

Specification/Informalities

[10] In view of the amendment to the specification, the objection as set forth in item [6] of the Office action mailed January 21, 2004 is withdrawn.

Claim Objections

[11] In view of the amendment to the claims, the objection to claim 13 as set forth in item [7] of the Office action mailed January 21, 2004 is withdrawn.

Claim Rejections - 35 USC § 101

[12] In view of the amendment to the claims, the rejection of claim 1 under 35 U.S.C. 101 as set forth in item [8] of the Office action mailed January 21, 2004 is withdrawn.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[13] Claim(s) 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 13 and 15 are indefinite in the recitation of "stringent conditions" as the specification does not define what conditions constitute "stringent." What hybridization conditions are considered "stringent" varies widely in the art depending on the individual situation as well as the person making the determination. While it is noted that the specification provides exemplary hybridization conditions that are considered by applicants to be "stringent" (see page 6, lines 11-15 of the instant specification), as these conditions are identified as being exemplary, it is unclear as to whether "stringent conditions" are also intended to be encompassed by the claims. As such it is unclear as to the scope of polypeptides that are encompassed by the claims.

Claim Rejections - 35 USC § 112, First Paragraph

[14] The written description rejection of claims 1 and 16-17 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [9] of the Office action mailed January 21, 2004 and for the reasons stated below.

[15] RESPONSE TO ARGUMENTS: Applicants argue the claims have been amended to limit the scope of claimed or recited proteins to those having PF1022 synthetase activity. Applicants argue a working example of the scope of claimed or recited proteins is exemplified by SEQ ID NO:2 and the specification describes routine methods for making and screening all the polypeptides encompassed within the scope of the claims. Applicants conclude that given the teachings of the specification and the experimentation to make and screen the claimed or recited proteins is routine, it would

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not require undue experimentation to make and screen all proteins as encompassed by the claims. Applicants' argument is not found persuasive.

It is the examiner's position that the single disclosed representative species, i.e., SEQ ID NO:2, fails to represent the entire genus of claimed variants of SEQ ID NO:2. In this case, while the genus of claimed variants of SEQ ID NO:2 is limited to those having PF1022 synthetase activity, the number of modifications to SEQ ID NO:2 in claim 1 part (b) is unlimited and the structures of the species encompassed by the genus are unlimited. Therefore, the genus encompasses any polypeptide structure having PF1022 synthetase activity. Even the species encompassed by the genus of polypeptides of claims 16-17 having a defined number of modifications are not described as there is no indication in the claims or the specification that "one modification" is intended to be interpreted as a modification of only a single amino acid. Thus, in accordance with MPEP 2111, which directs the examiner to give claims their broadest reasonable interpretation, even one substitution, deletion, addition, or insertion can be a modification to one amino acid or a number of contiguous amino acids. As such, the genus encompasses species having structures that are widely variant. MPEP § 2163 states, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus." As there is no way to predict a priori those structural variants of SEQ ID NO:2 that will have the desired PF1022 activity and only a single disclosed species of polypeptides having PF1022 activity has been disclosed, i.e., SEQ ID NO:2, the genus of claimed variants has not been adequately described in the specification.

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[16] The scope of enablement rejection of claim(s) 1, 13, and 15-17 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [10] of the Office action mailed January 21, 2004 and for the reasons stated below.

[17] RESPONSE TO ARGUMENTS: Applicants argue the claims have been amended to limit the scope of claimed or recited proteins to those having PF1022 synthetase activity. Applicants argue a working example of the scope of claimed or recited proteins is exemplified by SEQ ID NO:2 and the specification describes routine methods for making and screening all the polypeptides encompassed within the scope of the claims. Applicants conclude that given the teachings of the specification and the experimentation to make and screen the claimed or recited proteins is routine, it would not require undue experimentation to make and screen all proteins as encompassed by the claims. Applicants' argument is not found persuasive.

It is the examiner's position that the specification, while being enabling for SEQ ID NO:2, and a method for the production thereof by culturing a host cell transformed with an expression vector encoding SEQ ID NO:2, does not provide enablement for the broad scope of claimed polypeptides, which broadly encompasses any variant of SEQ ID NO:2 that has PF1022 synthetase activity. The examiner acknowledges the amendment to limit the scope of proteins to those having PF1022 synthetase activity. However, the examiner disagrees with applicants' assertion that only routine experimentation is required to make and screen all polypeptides as encompassed by the claims. In this case, the specification provides only a single working example of the broad scope of claimed polypeptides, i.e., SEQ ID NO:2. Other than this single

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example, neither the specification nor the prior art provides guidance as to single or multiple amino acids of SEQ ID NO:2 that can be modified by substitution, deletion, addition, and/or insertion and maintain the desired PF1022 synthetase activity. Thus, one of skill in the art is left to make and screen all possible variants of a 3,210 amino acid polypeptide to determine which of the vast number of variants has the desired PF1022 synthetase activity. There is a high level of unpredictability in modifying even a single amino acid of a protein's sequence with an expectation of obtaining a polypeptide having the desired activity, as evidenced by Branden et al. and exemplified by Witkowski et al. (references made of record in a previous Office action), the teachings of which are undisputed by applicants. Although methods for modifying a protein sequence and screening for those having the desired activity are known in the prior art, practicing these methods to identify those proteins having the desired activity from the vast number of variants of SEQ ID NO:2 is not routine in the art, particularly in view of the high level of unpredictability in altering a protein's sequence and the lack of guidance in the specification with regard to even a single amino acid of SEQ ID NO:2 that can be altered with an expectation of obtaining a polypeptide having the desired activity. Thus, undue experimentation would be required to make and screen all polypeptides encompassed by the scope of the claims.

Claim Rejections - 35 USC § 102

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[18] The rejection of claim(s) 1 and 15 under 35 U.S.C. 102(a) as being anticipated by Weckwerth et al. is maintained for the reasons of record as set forth in item [11] of the Office action mailed January 21, 2004 and for the reasons stated below.

[19] RESPONSE TO ARGUMENTS: Applicants argue the English language translation of Japanese Patent Application No. 2000-104291, filed April 6, 2000, to which the instant application claims foreign priority, was filed prior to the June 9, 2000 publication date of Weckwerth et al. Applicants argue that in view of this evidence, Weckwerth et al. is no longer available as prior art against the claimed invention. Applicants' argument is not found persuasive.

Contrary to applicants' argument, the earliest date of public availability of Weckwerth et al. is April 04, 2000. Applicants' attention is directed to the upper right-hand corner of page 17909 of Weckwerth et al., which states, "[p]ublished, JBC Papers in Press, April 4, 2000." According to the "JBC Papers in Press" website (www.jbc.org/pips/index.dtl; viewed on July 19, 2004), "**JBC Papers in Press**... ..will establish publication priority" (emphasis in original). As such, the date of earliest public availability of Weckwerth et al. is before the priority date of Japanese Patent Application No. 2000-104291. Consequently, the submission of an English language translation of Japanese Patent Application No. 2000-104291 fails to overcome the instant rejection.

[20] In view of the amendment to the claims, the rejection of claim(s) 1 and 13-14 under 35 U.S.C. 102(b) as being anticipated by Leitner et al. as set forth in item [12] of the Office action mailed January 21, 2004 is withdrawn. Leitner et al. teach isolation of a polypeptide having cyclosporin synthetase enzymatic activity. There is no teaching or

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suggestion in the prior that the polypeptide of Leitner et al. has PF1022 synthetase activity.

Claim Rejections - 35 USC § 103

[21] The rejection of claim(s) 13 under 35 U.S.C. 103(a) as being unpatentable over Weckwerth et al. in view of Leitner et al., Matsudaira, Wozney, and Aoyagi et al. is maintained for the for the reasons of record as set forth in item [13] of the Office action mailed January 21, 2004 and for the reasons stated below.

[22] RESPONSE TO ARGUMENTS: Applicants argue the English language translation of Japanese Patent Application No. 2000-104291, filed April 6, 2000, to which the instant application claims foreign priority, was filed prior to the June 9, 2000 publication date of Weckwerth et al. Applicants argue that in view of this evidence, Weckwerth et al. is no longer available as prior art against the claimed invention. Applicants argue Leitner neither discloses nor suggests the PF1022 synthetase protein and none of the remaining references remedies the deficiencies of the primary references, because they fail to teach or suggest the PF1022 synthetase protein. Applicants' argument is not found persuasive.

As stated above, the date of earliest public availability of Weckwerth et al. is before the priority date of Japanese Patent Application No. 2000-104291 and thus, contrary to applicants' assertion, Weckwerth et al. is available as prior art under 35 U.S.C. 102 (a). Weckwerth et al. teach a PF1022 synthetase protein. In view of the primary reference of Weckwerth et al. along with the secondary references of Leitner et

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al., Matsudaira, Wozney, and Aoyagi et al., the combination of which teaches all limitations of the claims and provides a motivation and reasonable expectation of success for recombinantly producing the polypeptide of Weckwerth et al., the claimed method would have been obvious at the time of the invention.

Conclusion

[23] Status of the claims:

- Claims 1-13 and 15-17 are pending.
- Claims 2-12 are withdrawn from consideration.
- Claims 1, 13, and 15-17 are rejected.
- No claim is in condition for allowance.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

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David J. Steadman, Ph.D.

Patent Examiner

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DS 07-22-04